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10/510,688	06/07/2005	John Vincent Dobson	Q84004	4030
23373 7590 01/06/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER SALZMAN, KOURTNEY R				
ART UNIT		PAPER NUMBER		
1795				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/510,688

Applicant(s)

DOBSON ET AL.

Examiner

KOURTNEY R. SALZMAN

Art Unit

1795

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30, 32-35, 39-50, 52-57, 59 and 60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30, 32-35, 39-50, 52-57, 59 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date October 8, 2004
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Summary

1. The amendment as filed on September 17, 2009 has been entered and fully considered.
2. In light of the amendment, the previous grounds are withdrawn.
3. Claims 30, 32, 39, 46, 47 and 50 have been amended. Claims 31, 36, 38, 51 and 58 have been cancelled. Claims 59 and 60 have been added.
4. Claims 30, 32-35, 39-50, 52-57, 59 and 60 are currently pending and have been fully considered.
5. As explained in the remarks regarding the necessity of the IB to furnish the references and certified copy, the IDS references not already approved will be so, and included in this action, and the certified copy will be marked as submitted.

Claim Rejections - 35 USC § 112

6. Claim 60 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 60 recites "taking a test sample of a quantity of a few millimeters..." but the specification provides support for only "a few millilitres" on page 8, lines 9-11. Furthermore, the collection of a length, as opposed to a test sample volume is indefinite.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 30, 32-35, 39-44 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over WILLIAMS et al (WO 95/04271), in view of SENDA et al (US 5,397,451).

Regarding claim 30, WILLIAMS et al teaches a sensor system for detection of an analyte in an aqueous solution (abstract) comprising:

- i. Sample receiving area (18 of figure 1)
- ii. At least three electrodes (12, 40 and 42 of figure 5). Reference number 12 is made of silver, as stated on page 11, lines 24-28. Reference number 40, the counter electrode, is made of platinum or gold and reference number, the reference electrode, 42 is made of silver on page 14, lines 17-31. The use of silver/silver chloride electrode is described specifically on page 14, lines 23-25.
- iii. Insulating substrate is reference number 10.
- iv. A power source is a potentiostat, as described on page 21, lines 19-22, adapted to apply a potential different between working and counter electrodes (12 and 40) with a characteristic potential.
- v. Output means, shown as reference numbers 38 and 80, as described on page 14, lines 8-11.
- vi. A pH buffering agent is provided to control the solution pH and a reference reagent is added to sufficiently concentrate the chlorine (p. 24,

lines 17-22). The reference reagent is stated on page 24, lines 18-22 to be sodium chloride. The adding of the reagent and agent is interpreted by the examiner to occur when contact occurs with the sensor body.

The limitation which requires the reference electrode to be formed "in situ" does not provide any structural difference than a reference electrode which is formed before operating conditions are employed. Moreover, the method of making the sensor is determined by the examiner to not have patentable weight as it does not structurally change the sensor, as claim 30 is an apparatus claim.

While WILLIAMS et al does teach the counter electrode to be made of multiple metals, WILLIAMS et al fails to explicitly teach the counter electrode to be made of silver.

SENDA et al teaches an electrode system on an insulating substrate, with counter and working electrodes made of silver in column 3, lines 29-33 and column 4, lines 65-68.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to make the counter electrode of WILLIAMS et al of silver, as in SENDA et al, because, silver is an inert electrically conductive metal, just as those listed in WILLIAMS et al, allowing for the same functionality to be provided by a silver counter electrodes as any other noble metal.

Regarding claim 32, WILLIAMS et al identifies the change and buffering of the pH to increase conductivity on page 20, lines 8-12.

Regarding claims 33 and 34, the measurement of ammonium in water is taught starting on page 23, line 25. The use of sodium chloride is stated to be used on page 24, lines 17-22. Page 21, lines 3-7 identifies a phosphate buffer solution as the chosen buffer, but the use of trisodium phosphate would be an obvious alternative as the selection of the buffer is to choose a pH to match the chemical reaction.

Regarding claim 35, since the measurement of chlorine, ammonium and heavy metals in water is taught in WILLIAMS et al, it would have been obvious to utilize the apparatus for the testing of nitrogen ions. The use of sodium chloride is stated to be used on page 24, lines 17-22. Page 21, lines 3-7 identifies a phosphate buffer solution as the chosen buffer, but the use of a pH around 6.8 would be an obvious alternative as the selection of the buffer is to choose a pH to match the chemical reaction.

Regarding claim 39, WILLIAMS et al teaches the application of voltage occurs from a potentiostat on page 21, lines 19-22.

Regarding claim 40, the application of a differential pulsed square wave voltammetric circuit would have been obvious to one of ordinary skill in the art as this is a well known method of voltage application in electrochemical cells.

Regarding claim 41, WILLIAMS et al teaches the entire apparatus to be portable for use in the field in claim 13.

Regarding claim 42, it would have been obvious to one of ordinary skill in the art to couple a display to the signal processing means in order to output the currents and concentrations read and generated by the sensor itself as a means of outputting the results because without the display there is no way to obtain information from the sensor.

Regarding claim 43, WILLIAMS et al states the substrate to be made of plastics, more specifically alumina, known to have hydrophobic properties on page 11, lines 17-20.

Regarding claim 44, all three electrodes are shown in figure 5 to be on the same substrate 10.

Regarding claim 49, WILLIAMS et al states on page 14, lines 21-29 that if the measured current, or solution conductivity of the instant application, is small the

addition of the reagents is then possible. Therefore, the reading of the conductivity occurs in addition to the information for calculating the concentration of the species.

9. Claims 50, 52-57, 59 and 60 (and 30, 32-35, 40-44 and 49 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over WILLIAMS et al (WO 95/04271), in view of SENDA et al (US 5,397,451) and KUYLS et al (Kuyls, Juozas, Jens A. Munk, Thomas Buch-Rasmussen, and Henrik E. Hansen. "The Preparation In Situ of a Silver-Silver Chloride Reference Electrode." *Electroanalysis* 6.11-12 (1994): 945-52

Regarding claim 50, WILLIAMS et al teaches a sensor system for detection of an analyte in an aqueous solution (abstract) comprising:

a. The application of a sample to the sensor element on page 21, lines 19-20 comprising:

vii. Sample receiving area (18 of figure 1)

viii. At least three electrodes (12, 40 and 42 of figure 5). Reference number 12 is made of silver, as stated on page 11, lines 24-28.

Reference number 40, the counter electrode, is made of platinum or gold and reference number, the reference electrode, 42 is made of silver on page 14, lines 17-31.

ix. Insulating substrate is reference number 10.

- b. Adding the test solution of pH buffering agent is provided to control the solution pH and a reference reagent is added to sufficiently concentrate the chlorine (p. 24, lines 17-22), by way of applying the solution to the sensor. The reference reagent is discussed to be sodium chloride on page 24, lines 18-22. Page 21, lines 3-7 identifies a phosphate buffer solution as the chosen buffer, but the use of trisodium phosphate would be an obvious alternative as the selection of the buffer is to choose a pH to match the chemical reaction. The connection of the silver electrode and the excess sodium chloride present in the reagent will cause the formation of the silver-silver chloride electrode as discussed on page 14, lines 23-25 and also as discussed below.
- c. Connection to a power source is a potentiostat, as described on page 21, lines 19-22, adapted to apply a potential different between working and counter electrodes (12 and 40) with a characteristic potential.
- d. Output means, shown as reference numbers 38 and 80, as described on page 14, lines 8-11. The application of the power is started following the introduction of the solution as stated in column 21, lines 19-22, therefore, once the power is applied output begins, encompassing quasi-steady state (before vibration) and during steady state.

While WILLIAMS et al does teach the counter electrode to be made of multiple metals, WILLIAMS et al fails to explicitly teach the counter electrode to be made of silver. WILLIAMS et al also fails to explicitly teach the use of a trisodium

phosphate buffering agent and the creation of the silver-silver chloride reference electrode in situ.

SENDA et al teaches an electrode system on an insulating substrate, with counter and working electrodes made of silver in column 3, lines 29-33 and column 4, lines 65-68.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to make the counter electrode of WILLIAMS et al of silver, as in SENDA et al, because, silver is an inert electrically conductive metal, just as those listed in WILLIAMS et al, allowing for the same functionality to be provided by a silver counter electrodes as any other noble metal.

KUYLS et al teaches the preparation of a silver-silver chloride reference electrode through the use of a phosphate buffer and sodium chloride reagent in situ in the abstract. The introduction also details the use of a constant potentiometric source, as is required by the instant application. The pure silver electrode is the starting point for the synthesis of the silver-silver chloride reference electrode in situ using the buffer and reagent.

At the time of the invention, it would have been obvious to create the silver-silver chloride reference electrode of WILLIAMS et al in the sensor of WILLIAMS et al

and SENDA, in situ, as shown by KUYLS et al because as stated on page 8 of KUYLS et al, in situ formation of the reference electrode shows improved reproducibility and stability of the potential in the last paragraph.

When claim 30 and dependent claims are interpreted to give patentable weight to the formation of the reference electrode in situ, the interpretation utilized in the rejection of claim 50 would be applied.

Regarding claim 52, WILLIAMS et al teaches on page 24, lines 19-22, that enough sodium chloride is used to create a solution with sufficient chlorine concentration for high efficiency. It would have been obvious to add any amount of sodium chloride which makes the solution detectable.

Regarding claims 53 and 54, the measurement of ammonium in water is taught starting on page 23, line 25. The use of sodium chloride is stated to be used on page 24, lines 17-22. Page 21, lines 3-7 identifies a phosphate buffer solution as the chosen buffer, but the use of trisodium phosphate would be an obvious alternative as the selection of the buffer is to choose a pH to match the chemical reaction.

Regarding claim 55, since the measurement of chlorine, ammonium and heavy metals in water is taught in WILLIAMS et al, it would have been obvious to utilize

the apparatus for the testing of nitrogen ions. The use of sodium chloride is stated to be used on page 24, lines 17-22. Page 21, lines 3-7 identifies a phosphate buffer solution as the chosen buffer, but the use of a pH around 6.8 would be an obvious alternative as the selection of the buffer is to choose a pH to match the chemical reaction.

Regarding claim 56, it would have been obvious to one of ordinary skill in the art to couple a display to the signal processing means in order to output the currents and concentrations read and generated by the sensor itself as a means of outputting the results because without the display there is no way to obtain information from the sensor.

Regarding claim 57, WILLIAMS et al teaches the reagents to be encapsulated in a soluble film, allowing for the reagents to be dispersed into the sample upon dissolution and contact on page 20, lines 8-25.

Regarding claim 59, the introduction to KUYLS et al teaches the reference electrode to be of use in steady state potential systems and WILLIAMS et al discloses a steady-state, as is obvious to include.

Regarding claim 60, KUYLS et al teaches the use of a silver-silver chloride sensor to be of use with same analyte samples (in the Introduction) and

WILLIAMS et al teaches on page 12 for the active surface or reagent area of the sensor to be on the order of 10 millimeter squared. With a testing area on the order of millimeters large scale testing is not applicable, therefore, it would be obvious to have a small sample size around millimeters in area or milliliters in size. WILLIAMS et al also discloses a container to be of use for holding the sample at the bottom of page 12 and top of page 13. Furthermore, while WILLIAMS et al does address dynamic sample movement, it is not required of the sample as the movement is preferential, as stated in the first aspect on page 6, lines 13-25, where it is stated, the electrodes "can be mounted for application of vibration to it".

10. Claims 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over WILLIAMS et al (WO 95/04271), in view of SENDA et al (US 5,397,451) (and in the alternative KUYLS et al), as applied to claim 30, in further view of BOHS et al (US 5,399,256).

WILLIAMS et al and SENDA et al teach all the limitations of claim 30. WILLIAMS et al fails to explicitly show circular concentric electrodes and a temperature sensing system. However, SENDA et al teaches concentric electrodes as shown in figure 2 but is not clear as to the functionality or even the reference numbers shown and therefore, does not teach concentric electrodes and a temperature sensing system explicitly either.

Regarding claims 45-47, BOHS et al teaches an electrochemical detection cell in figures 7-12 with concentric electrode orientations. Regarding claim 46, figure 11 shows a central or first electrode 242, with second and third electrodes concentrically organized, reference numbers 244 and 246. Regarding claim 47, figure 17 shows an electrode with pieces insulated from each other while the concentric shaping of the outer electrodes is shown in figure 11.

At the time of the invention, it would have been obvious for one of ordinary skill in the art to organize the electrodes of WILLIAMS et al and SENDA et al in the orientations of BOHS et al because they are shown to be arrangements known in the art which provide the same functionality.

Regarding claim 48, BOHS et al teaches the control of temperature of the sample in column 9, lines 23-32.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to supply the temperature detection means of BOHS et al to the electrochemical cell of WILLIAMS et al and SENDA et al because BOHS et al states in column 9, lines 27-30, temperature control ensures optimal results and experimental precision from test to test.

Response to Arguments

11. Applicant's arguments with respect to claims 30, 32-35, 39-50, 52-57, 59 and 60 have been considered but are moot in view of the new ground(s) of rejection.

New grounds of rejection are necessitated by amendment, as the requirement for all the electrodes to be only made of silver and for in situ formation of the reference electrode necessitated the addition of reference SENDA et al and KUYLS et al.

12. In response to the applicant's arguments to the application of WILLIAMS et al:

e. Applicant argues on pages 11 that the reagents added in WILLIAMS et al are not for creating a reference electrode of silver-silver chloride. Prior to the amendment this was not a claimed aspect of the invention, as it did not require the formation of the silver-silver chloride reference electrode through the use of the reagents. This is addressed in the above rejections, both with WILLIAMS et al (and in the alternative, as with independent claim 30) and without.

f. Applicant argues on pages 11 and 12 repeatedly that WILLIAMS et al only teaches the sensor for use in a flowing or shaken sample, not the small, quiescent sample which is contended to be present in the instant application. Most notably, outside of the addition of claim 60 in this most recent amendment, there is no claim language which requires a quiescent or any size sample for use, or that vibration can not be present. Moreover, WILLIAMS et al also does not require the use of vibration, as in the use of the first aspect of the invention, but primarily talks about the control of the vibration. Therefore, it is not outside

the realm of application for the vibration to be controlled so no vibration is felt.

On page 12, applicant as grouped WILLIAMS et al with the "hulk or flow through systems", while it should be pointed out that the system of WILLIAMS et al is also portable as discussed in the claims above.

g. Applicant argues on page 12 that WILLIAMS et al teaches the combination of a counter electrode and reference electrode. While WILLIAMS et al does teach the combination of the two electrodes in a passage not cited by the examiner in the action, WILLIAMS et al also cites two separate electrodes to be of use.

h. Applicant argues on page 11 that BOHS et al does not teach pure silver electrodes. BOHS et al is not relied upon in the rejection to teach that aspect.

i. Applicant also argues on page 12 that BOHS et al fails to teach a mobile system but rather a flow through system. BOHS et al is primarily used to teach electrode orientation in the rejection, therefore the use of the system is a fixed location or for a flow through application, is not relevant to the claimed language, as this is not claimed in the claims where BOHS et al is applied.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KOURTNEY R. SALZMAN whose telephone number is (571)270-5117. The examiner can normally be reached on Monday to Thursday 6:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/
Primary Examiner, Art Unit 1795

krs
12/31/2009